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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,605	09/29/1998	TOM DE VRINGER	98.554	8895

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/155,605

Applicant(s)

Vringer

Examiner

Gollamudi Kishore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 4, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The request for the extension of time and response filed on 9-4-02 are acknowledged.

Claims included in the prosecution are 1-19.

Claim Rejections - 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 521 562 in view of EP 0 678 295, EP 0159237, GB 2002319, JP 05194253 by themselves or in combination.

EP 0521 562 teaches instant reverse vesicles containing sucrose fatty acid esters (note the abstract, Examples and claims). What this reference lacks is the teachings of dehydration of these vesicles to obtain a powder.

EP 0678 295 teaches that vesicular preparations can be lyophilized to form powders (note Example 1 and claims 1 and 7).

EP 0159237 teaches that emulsions (micelles) can be freeze-dried to form powders which are easier to handle than emulsions (note the abstract).



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GB teaches that dehydration of lipid vesicles (liposomes) to prepare a stable powder which can be stored for longer periods of time (note the abstract).

JP 05194253 teaches the preparation of a powder of reverse micelles containing a surfactant (note the abstract).

The removal of solvent from the vesicles of EP 562 to form powders would have been obvious to one of ordinary skill in the art since EP 295, 237 and GB each teach that vesicular preparations can be dehydrated and because of the advantages of powders compared to liquids taught by EP 237 and GB; one skilled in the art would be motivated to dehydrate the vesicles of EP 562 with the expectation of obtaining similar powders. One of ordinary skill in the art would be motivated further to dehydrate the reverse micelles containing surfactants to prepare a powder since JP (253) teaches that powders of reverse micelles can be prepared.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant does not provide any arguments regarding the primary reference's teachings of reversed vesicles. Applicant's arguments pertain to the secondary references's teachings and the lack of motivation to remove the solvent from EP (562)'s reverse vesicles. In this context, the examiner regrets the inadvertent citing of the wrong pages in EP 295 in the previous action. Applicant argues that EP 295 does not teach powders of reverse vesicles. Applicant argues that EP 237 teaches powders of oil in water emulsions. Applicant argues that GB teaches dehydration of liposomes and in fact teaches away from a powder



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of reversed vesicles and points out to page 1, lines 39-43. Applicant further argues that JP teaches reverse micelles and micelles are not vesicles. These arguments are not found to be persuasive since the references clearly show that powders can be prepared from micelles, reverse micelles and vesicles and therefore, one of ordinary skill in the art would be motivated to make powders of the reverse vesicles of EP 562 with a reasonable expectation of success. With regard to applicant's arguments that GB teaches away, the examiner is unable to find how the statement on page 1 in GB can be considered as teaching away since GB shows successful preparation of powders from vesicular preparations. Furthermore, this statement cannot be construed as teaching away since in reverse vesicles, the hydrophobic moiety of the lipid is inside and hydrophilic moiety outside; therefore, 'oily sticking residue' referred to in GB is not applicable here. In fact, the contrary is true; that is since there is no oily sticking residue is not outside in reverse vesicles, one would expect the powder preparations of reverse vesicles to be much easier than the preparation of powders from regular vesicles (liposomes). Applicant's arguments that reverse micelles and reverse vesicles are distinct entities with different biological properties are not persuasive. Although they are different (micelles have a single layer as opposed to a bilayer in vesicles), they share one fundamental important property; that is the hydrophobic moiety of the lipids in micelles is oriented outside toward the hydrophobic medium just as in reverse vesicles.

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Applicant argue that the presently claimed reverse vesicle powder when dispersed in a apolar vehicle such as s biodegradable oil, retains its vesicular structure with a yield greater than when the reversed vesicles are prepared directly in the biodegradable oil. This argument is not found to be persuasive since both product and process claims do not recite this limitation; furthermore, the vesicular preparation in the primary reference (EP 0 521 562) is the same as in instant application. In summary:- the prior art of record clearly indicates the knowledge in the art of preparing the reverse vesicles and the preparation of powders by dehydrating either micelles or vesicles, and one would be motivated to remove the solvent from reverse vesicles of EP 562 to prepare powders with a reasonable expectation of success.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

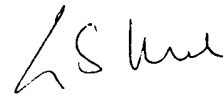
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

November 6, 2002